

**REMARKS**

Applicants have not amended any claims in this response.

Claims 18 to 21 were previously cancelled,

Claims 1-17 and 22-26 are pending in the application.

**Allowable Subject Matter**

Applicants acknowledge the Examiner's allowance of Claims 17, 23-25.

The Office Action dated July 9, 2009 indicated that claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants thank the Examiner for the recognition of allowability of claim 10.

**Double Patenting Rejection**

Claims 1 and 5 are rejected under the doctrine of non-statutory obviousness-type double patenting, as being unpatentable over claims 1 and 6 of U.S. Patent No. 7,220,249.

Claims 1-16, 17, 19 and 22-26 are rejected under the doctrine of non-statutory obviousness-type double patenting, as being unpatentable over claims 1-15 of U.S. Patent No. 7,128,726.

Claims 1-16, 17, 19 and 22-26 are rejected under the doctrine of non-statutory obviousness-type double patenting, as being unpatentable over claims 1-28 of U.S. Patent No. 6,699,217.

Applicant will file Terminal Disclaimers if warranted, upon allowance of the claims, which address these rejections.

**Claims Rejections – 35 USC § 103**

Claims 1-9, 11-16, 19, 22, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,632,732 to Szabo et al. (“Szabo”) in view of US Patent No. 5,509,907 to Bevilacqua (“Bevilacqua”).

These rejections are respectfully traversed.

Of the claims rejected, claims 1 and 5 are independent, with the remaining claims dependent thereon.

Claim 1 is directed to a safety needle assembly and recites, among other things:

*said shield comprising at least one support wall, and a channel mounted to said support wall, said channel having a top wall and opposed first and second sidewalls extending from said top wall, and at least one resiliently deflectable cannula finger lock projecting from said first sidewall angularly toward said top wall,*

*wherein said channel can be selectively mounted to said support wall in one of a plurality of orientations in relation to one another.*

Claim 5 is directed to a safety needle assembly and recites, among other things:

*said shield comprising at least one support wall, and a channel mounted to said support wall, said channel having a top wall and opposed first and second sidewalls extending from said top wall, and at least one resiliently deflectable cannula finger lock,*

*wherein said top wall of said channel comprises mounting structure for mounting said channel to said support wall, whereby said channel can be disposed in either a first orientation or in a second orientation relative to said support wall for altering positions of said channel relative to said needle cannula.*

Applicants agree with the Examiner that Szabo fails to disclose teach or suggest at least the claimed features of at least one resiliently deflectable cannula finger lock.

The Examiner now takes the position in that it would have been obvious to one of ordinary skill in the art to combine the device of Szabo with the teachings Bevilacqua because Bevilacqua discloses an easy and effective way to secure the needle to the needle shield to prevent accidental pricking.

In contrast Szabo teaches a needle shield which prevents accidental pricking by encompassing/surrounding the needle and as such does not require any securement of the needle to the shield.

Furthermore the applicants maintain their position as expressed in the correspondence dated April 10, 2009 in that:

a) In the absence of hindsight, one skilled in the art would not have been motivated by Szabo to look at or for inclusion of at least one resiliently deflectable cannula finger lock, and thus would have no reason to look to the Bevilacqua reference.

b) Szabo teaches away from the addition of a permanent locking feature such as a resiliently deflectable cannula finger lock.

c) Furthermore the addition of at least one resiliently deflectable cannula finger lock to the needle shield of Szabo changes the principle of operation, and destroys the function of the Szabo device.

The office action dated March 31, 2010 states (emphasis added):

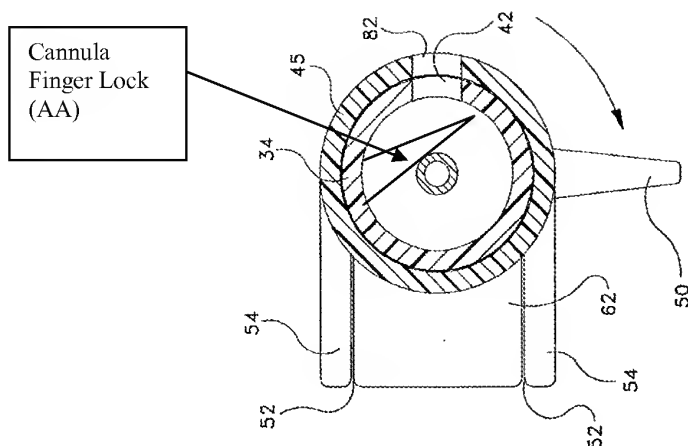
“The examiner has read through applicant argues and still maintains his rejection because the examiner feels that adding a cannula lock wouldn't destroy or defeat the purpose of Szabo. One of ordinary skill in the art would understand how to make a cannula lock that could be re-useable or even could lock the needle in the shield before use. The examiner also feels that the cannula finger lock could be used to prevent the needle from piercing the walls of the shield and thus be used as a centering device as well as a locking device. Therefore the examiner feels that one of ordinary skill in the art would be able to modify the device of Szabo to add a cannula finger lock since this element is so well known in the art (see IDS as well as Bevilacqua) and could make the locking or holding element a permanent holding device or a temporary needle holder since the cannula lock could be used before use.”

Applicants respectfully disagree one of ordinary skill in the art would understand how to make a cannula finger lock that could be re-useable inside the shield of Szabo.

First Bevilacqua teaches a syringe needle guard assembly which provides a needle locking structure to permanently lock the needle within the guard assembly and prevent removal or reuse of the guard assembly (see Col. 2 lines 3 to 7 and Col. 3 lines 55 to 59).

Thus Bevilacqua teaches away from a reusable locking mechanism.

Second it is unclear how the addition of a cannula finger lock (AA) inside the shield (34) of Szabo can be made to be reusable when the cannula finger lock would be fully enclosed within shield (43) as depicted in a modified Fig. 8 on the next page.



Modified FIG. 8 of Szabo

Thus one of ordinary skill would understand that the operator of the combined device would have no access to disengage the cannula finger lock (AA) when attempting to reuse the device.

Szabo discloses several benefits of the shield over the existing art (see Col. 3 lines 11 to 15). These benefits include for example:

- (1) The ability to reuse, reshield and relatch the shield, by reversibly rotating the latch around the shield from the latched (Fig.7) to unlatched position (Fig.8) and back to the latched position.
- (2) The ability for the user to readily visually ascertain if the shield is open or closed (hence is the cannula safely shielded) by looking at the alignment of the elongated slots.

In regard to benefit (1) Szabo teaches away from the use of a permanent locking mechanism for the shield which prevents reuse, reshielding and relatching of the shield.

In regard to benefit (2) the incorporation of a secondary locking element such as at least one resiliently deflectable cannula finger lock inside the shield of Szabo would destroy the ability for the user to readily visually ascertain if the shield is open or closed by looking at the alignment of the elongated slots.

The office action dated March 31, 2010 also states (emphasis added):

“The examiner feels that Bevilacqua provides proper motivation and a benefit for adding a cannula finger lock to a needle shield since it would prevent the cannula from being accidentally released. One of ordinary skill in the art would understand that the cannula finger lock would provide an extra benefit to any needle shielding device that lacked such a structure (i.e. Szabo). The examiner also feels that the cannula lock wouldn't be redundant to the device of Szabo since the cannula lock would provide an extra locking element to ensure the needle is locked into the shield.”

A cannula finger lock would be redundant to the device of Szabo as the misalignment of elongate slots (82) and (42) ensures that the cannula is entrapped within shield (34) (see Fig. 8).

Thus one skilled in art would have absolutely no motivation to add an additional “redundant” cannula retention feature such as at least one resiliently deflectable cannula finger lock to trap the cannula in the shield of Szabo.

A modification of the Szabo shield to have at least one resiliently deflectable cannula finger results in a change in the principle of operation of the shield if not rendering the shield unsatisfactory for its intended purpose.

The Examiner should also note, according to MPEP §2143.01 Section VI, that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Furthermore, according to MPEP §2143.01 Section V, that if a proposed modification would render the prior art invention modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

The office action dated March 31, 2010 further states (emphasis added):

"The examiner further relies on MPEP and the recent KSR case when dealing with combining structural elements that are taught in the prior art. See MPEP section 2141 and ["In *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." Id. at -, 82"]

Applicants respectfully resubmit that the examiner proposes the addition of a second "redundant" locking element (a cannula finger lock) to the device of Szabo and not a substitution of an element.

The office action dated March 31, 2010 also states (emphasis added):

"USPQ2d at 1395. (2) "In *Anderson 's-Black Rock, Inc. v. Pavement Salvage Co.*, . . . [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation." Id. at -, 82 USPQ2d at 1395. (3) "[I]n *Sakraida v. AG Pro, Inc.*, the Court derived . . . the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." MPEP section 21410.3 - "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR International Co. v. Teleflex Inc.*, 550 U.S. -, -, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into accounts "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. at -, 82 USPQ2d at 1396.

Applicants submit that the proposed modification of the shield of Szabo to add a cannula finger lock, as taught by Bevilacqua would prevent the Szabo needle shield element from performing the same function it had been known to perform. For example such as the ability to reuse, reshield and relatch the shield of Szabo, by reversibly rotating the latch around the shield from the latched (Fig.7) to unlatched position (Fig.8) and back to the latched position

For these reasons, applicants submit that independent claim 1 and dependent claims 2-4 10-16, and independent claim 5 and dependent claims 6-9 and 26, are patentable over the cited references.

**Conclusion**

In view of the remarks herein, applicants submit the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicant's agent at the telephone number set forth below.

Respectfully submitted,

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